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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
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| 10/009,097 | 05/21/2002 | Judith Marlett | WARF-0174 | 5531 |
| 23377 | 7590 | 03/23/2004 | | |
| WOODCOCK WASHBURN LLP ONE LIBERTY PLACE, 46TH FLOOR 1650 MARKET STREET PHILADELPHIA, PA 19103 | | | | EXAMINER |
| | | | | PRATS, FRANCISCO CHANDLER |
| | | | ART UNIT | PAPER NUMBER |
| | | | 1651 | |

DATE MAILED: 03/23/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

| Application No. | Applicant(s) | |
|-------------------|----------------|--|
| 10/009,097 | MARLETT ET AL. | |
| Examiner | Art Unit | |
| Francisco C Prats | 1651 | |

*– The MAILING DATE of this communication appears on the cover sheet with the correspondence address –
Period for Reply*

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- Responsive to communication(s) filed on ____.
- This action is FINAL. This action is non-final.
- Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- Claim(s) 1-27 is/are pending in the application.
4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- Claim(s) ____ is/are allowed.
- Claim(s) 1-27 is/are rejected.
- Claim(s) ____ is/are objected to.
- Claim(s) ____ are subject to restriction and/or election requirement.

Application Papers

- The specification is objected to by the Examiner.
- The drawing(s) filed on ____ is/are: a) accepted or b) objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
a) All b) Some * c) None of:
 - Certified copies of the priority documents have been received.
 - Certified copies of the priority documents have been received in Application No. 09/328,611.
 - Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- Notice of References Cited (PTO-892)
- Notice of Draftsperson's Patent Drawing Review (PTO-948)
- Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)
Paper No(s)/Mail Date 7-22-02.
- Interview Summary (PTO-413)
Paper No(s)/Mail Date. ____.
- Notice of Informal Patent Application (PTO-152)
- Other: ____.

DETAILED ACTION

Claims 1-27 are presented for examination.

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless -

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-4, 6-11 and 18-23 are rejected under 35 U.S.C. 102(b) as being anticipated by Laidlaw et al (J. Chem. Soc. 1950, pages 528-534) (Laidlaw I).

Laidlaw I discloses a polysaccharide preparation from *Plantago ovata* Forsk, designated as "PII", said preparation comprising 80% xylose, 14% arabinose and no rhamnose, said preparation being highly viscous. See page 529. Thus, Laidlaw I's composition contains all of the claimed ingredients in the claimed amounts. Note specifically that the recitation "comprising less than about 2% (by weight) rhamnose" encompasses zero. Note further that the reference clearly anticipates the dosage amounts recited in the claims since any amount would have some beneficial effect. Note further that the product clearly

would preparable by the method recited in claim 13.

Claim 12 is rejected under 35 U.S.C. 102(b) as being anticipated by Laidlaw et (J. Chem. Soc. 1949, pages 1600-1607) (Laidlaw II). Specifically, Laidlaw II discloses a polysaccharide preparation from *Plantago ovata* Forsk, designated as "PII", said preparation comprising 46% xylose, 7% arabinose and 40% 2-D-galacturonosido-L-rhamnose, a disaccharide comprised of equal parts galacturonic acid and rhamnose. See page 1600. Thus, Laidlaw II's "PI" composition contains 20% of each of galacturonic acid and rhamnose. Laidlaw II's composition therefore contains all of the claimed ingredients in the claimed amounts.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various

claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 24-27 rejected under 35 U.S.C. 103(a) as being unpatentable over Kennedy et al (Carb. Res. 75:265-274 (1979)) in view of Laidlaw et al (J. Chem. Soc. 1950, pages 528-534) (Laidlaw I). Note specifically that the therapy claims encompass administration of unfractionated psyllium for constipation. Kennedy discloses that psyllium is known to have therapeutic properties with respect to large bowel disorders. As also discussed above, psyllium is known to contain the polysaccharide recited in the claims. Thus, taken together, the references clearly provide motivation for administering a product containing the claimed therapeutic agent to the claimed patient.

Claim Rejections - 35 USC § 102/103

Claims 18-23 are rejected under 35 U.S.C. § 102(b) as anticipated by or, in the alternative, under 35 U.S.C. § 103(a) as obvious over Kennedy et al (Carb. Res. 75:265-274 (1979)).

Kennedy discloses a process whereby a polysaccharide fraction is obtained from psyllium by initial alkali treatment followed by acidification. See page 266, section entitled "Alkaline fractionation." While Kennedy uses a different hydroxyl ion concentration (1.2 M NaOH) than recited in claim 13 (up to .015 to 1.0 M hydroxyl ion), the slight difference in concentration of extracting solvent would not have been expected to have affected the makeup and properties of the resulting product. Consequently, the claimed product appears to be anticipated by the reference.

However, even if the reference product and the claimed product are not one and the same and there is, in fact, no anticipation, the reference product would, nevertheless, have rendered the claimed product obvious to one of ordinary skill in the art at the time the claimed invention was made in view of the fact that a slight difference in extraction pH would have reasonably been expected to have resulted in nominal changes in the properties of the product produced by that extraction. Thus the claimed invention as a whole was clearly *prima facie* obvious especially in the absence of sufficient, clear, and convincing evidence to the contrary.

Double Patenting

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer cannot overcome a double patenting rejection based upon 35 U.S.C. 101.

Claim 5 is rejected under 35 U.S.C. 101 as claiming the same invention as that of claim 5 of prior U.S. Patent No. 6,287,609 B1. This is a double patenting rejection.

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 1-4, 6-12 and 18-23 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,287,609. Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the patented claims have a narrower scope than the claims under examination, the patented claims contain all of the limitations present in the claims under examination. Thus, despite the differences in scope of the two sets of claims, the patented claims, if they were prior art, would anticipate the claims under examination. A terminal disclaimer is clearly required in such a situation.

Claims 13-17 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over the claims of U.S. Patent No. 6,676,979. Although the conflicting claims are not identical, they are not patentably distinct from each other because, while the patented claims have a narrower scope than the claims under examination, the patented claims contain all of the limitations present in the claims under examination. Thus, despite the differences in scope of the two sets of claims, the patented claims, if they

were prior art, would anticipate the claims under examination. A terminal disclaimer is clearly required in such a situation.

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Francisco C Prats whose telephone number is 571-272-0921. The examiner can normally be reached on Monday through Friday, with alternate Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael G Wityshyn can be reached on 571-272-0926. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Francisco C Prats
Primary Examiner
Art Unit 1651

FCP